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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,752	08/17/2006	Marco E. Bianchi	2507-1082	7984

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
03/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,752	BIANCHI, MARCO E.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2009 and 12 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19* is/are pending in the application.

4a) Of the above claim(s) *16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks filed March 12, 2010 and November 27, 2009 are acknowledged.

   Claims 1-11 have been canceled.

   Claim 12 has been amended.

   Claims 12-19 are pending.

   Claims 12-15 are under examination wherein the elected species of HMG box binding molecule is "an HMG box binding antibody" and the elected species of vascular disease is "due to restenosis after blood vessel damage, including those events that occur after coronary and/or carotid angioplasty, with or without stent positioning, angiographic surgery, and surgery using catheters".

   Claims 16-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group of invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 20, 2009.

2. The rejections of record can be found in the Office Action mailed May 27, 2009.

   Upon further consideration the previous "provisional" rejection under 35 U.S.C. 102(e) over copending Application No. 10/471641 (US 20040136979) has been withdrawn. As stated in the previous Office Action on apge 4, Section 10, applicatoin number 10/471641, ***corresponds to publication number US 20040136979***. Provisoinal rejections under 35 U.S.C. § 102(e) are appropriate when the reference application is not yet published, not when it has been published. Thus, a proper rejection under 35 U.S.C. § 102(e) over copending Application No. 10/471641 (US 20040136979) has been put forth in its place.

Rejections Maintained

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

   A person shall be entitled to a patent unless –

   (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bianchi et al. (WO 2002/074337), essentially for the reasons of record as put forth in the Office Action mailed May 27, 2009.

Applicant argues Bianchi does not anticipate the claimed invention for the following reasons:

"BIANCHI describes HMGBI as a chemoattractant that causes cell shape changes and cytoskeleton reorganization and induces the migration cells, such as smooth muscle cells and fibroblasts…BIANCHI, however, fails to teach or suggest that an HMG box protein could play any role in cell proliferation." Applicant then goes on to describe how the instant specification discloses that hmgb1 induces endothelial and smooth muscle cell proliferation and reiterates: "BIANCHI fails to teach or suggest that HMGBI protein would have any effect on cell proliferation, and more specifically, endothelial or smooth muscle cell proliferation. In distinction from the chemoattractant properties disclosed in BIANCHI, instant claim 12 is directed to a method for treating vascular diseases related to endothelial and smooth muscle cells proliferation."

(see remarks page 5, last paragraph through page 6, applicant's emphasis shown)

Applicant's argument has been considered, but has not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed May 27, 2009.

Applicant's emphasis on the differences of the teaching of Bianchi versus the instant specification with respect to the effect of HMG box binding molecules on endothelial and smooth muscle cells, i.e., the effect of hmgb1 on cell migration versus proliferation, is not found convincing because it does not serve to distinguish the claimed method from the prior art.

As stated in the previous Office Action in Section 4, "Bianchi teaches the treatment of vascular disease, for example restenosis after blood vessel damage, by administering an anti-HMG box antibody (see page 6, 2nd paragraph, pages 24-26 and claims 1-6)."

Thus, the prior art teaches the same method steps as claimed in the instant invention directed to the same purpose, i.e., administering to a subject in need thereof a therapeutically active amount of an HMG box binding molecule, wherein the subject has, e.g., restenosis after blood vessel damage. Applicant has not put forth a convincing argument based on objective evidence and/or sound scientific reasoning to show a manipulative difference between claimed the method steps and the teachings of the prior art. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Moreover, it is worth noting that the prior art did teach that vascular disorders, such as atherosclerosis and restenosis after coronary angioplasty, involve ***both*** cell division ***and*** cell migration of endothelial smooth muscle cells (see pages 4-5 of Bianchi).

Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979).

In conclusion, given the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

   A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

   Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 12-15 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 26 and 29 of copending Application No. 10/471641 (US 20040136979), essentially for the reasons of record as put forth in the Office Action mailed May 27, 2009.

   Applicant argues the claims of the '641 application are patentably distinct from the instant claims because the claims of the '641 application are directed to "a method of treating arterial stenosis or restenosis in an individual, comprising administering to an individual at risk of developing or having arterial stenosis or restenosis a molecule that blocks interaction of an HMGB1 protein on its receptors…" while the instant claims are directed to "directed to a method for treating vascular diseases related to endothelial and smooth muscle cells proliferation. This stands in distinction from treating arterial stenosis or restenosis." (see remarks page 7, last paragraph – page 8, 1st paragraph, applicant's emphasis shown).

Applicant's argument has been considered, but has not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed May 27, 2009.

In essence, applicant has not convincingly distinguished the reference prior art claims in view of the knowledge in the art (treating arterial stenosis or restenosis by administering an HMG box binding molecule) from the instant claims (treating vascular diseases related to endothelial and smooth muscle cells proliferation, wherein the vascular diseases are due to atherosclerosis and/or restenosis after blood vessels damage by administering an HMG box binding molecule).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/471641 (US 20040136979), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

8. Claims 12-15 stand directed to an invention not patentably distinct from claims 10, 26 and 29 of commonly assigned Application No. 10/471641 (US 20040136979) essentially for the reasons of record as put forth in the Office Action mailed May 27, 2009 at page 4, Section 8.

While applicant does not appear to have addressed this issue in their remarks, presumably applicant believes their attempted rebuttal of the rejection under obviousness-type double patenting rejection renders this issue moot. However, for the same reasons these rejections were maintained, this issue is still relevant to the instant application.

New Grounds of Rejection

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the

effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Application No. 10/471641 (US 20040136979).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bianchi teaches the treatment of vascular disease, for example restenosis after blood vessel damage, by administering an anti-HMG box antibody (see, e.g., claim 4).

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachary Skelding/
Examiner, Art Unit 1644